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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,838	07/20/2005	Willem Ferdinand Nieuwenhuizen	VER-194XX	9011

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EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,838	NIEUWENHUIZEN, WILLEM FERDINAND	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-15* is/are pending in the application.

4a) Of the above claim(s) *6-9,12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 14-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/25/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 10/22/2010, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by US 6239297 ('297) is maintained.

Applicant argues that the amended claims indicate that the sphingolipid is orally administered to subjects whose intestinal flora is out of balance. Because oral administration of a sphingolipid to subjects whose intestinal flora is out of balance is not disclosed by '297, the instant method is distinct over '297.

Applicant's arguments have been fully considered but are not found persuasive. '297 teaches oral administration of sphingosine to humans (mammals) as an antifungal or as an immunosuppressive agent (abstract; col 4, line 64 to col 5, line 2; col 7, lines

34-51; col 15, lines 17-20; col 17, lines 42-45). The intestinal flora of a given person is regularly out of balance. The patient population to which the sphingosine of '297 will be administered is large, i.e. the patient population are patients in need of an antifungal or immunosuppressive agent. Owing to the ubiquity of humans with intestinal flora out of balance, and the fact that the patient population of '297 is large, the patient population of '297 will inherently comprise members whose intestinal flora is out of balance. Thus, the method taught by '297, i.e. orally administering sphingosine to patients in need of antifungals or immunosuppressants, inherently involves orally administering the sphingosine to humans who intestinal flora is out of balance. As a composition cannot be separate from its properties, the sphingosine administered to these patients will inherently improve their intestinal flora. In short, the method of '297 inherently involves administering sphingosine to humans whose intestinal flora is out of balance, and this method will inherently improve the intestinal flora of these patients, even though '297 does not appreciate this property of the composition. "'[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

Note, the Examiner interprets the pharmaceutical composition to read on Applicant's "food in which one or more sphingolipids… are overabundant". The instant specification does not have a limiting definition of "food" but states at page 8, lines 10-11 that "the composition of a food does not essentially differ from a nutritional supplement". The pharmaceutical composition of '297 is a form of a nutritional supplement.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5 are rejected under 35 U.S.C. 102(a) as being unpatentable over JP 2003-252765 (JP '765; machine translation provided). JP '765 teaches that a composition comprising sphingolipid may be used to treat movement of intestine malfunction (claim 1). JP '765 teaches adding the composition to food (claim 4) or in a pharmaceutical formulation (paragraph 16). JP '765 teaches oral administration of the composition (paragraph 16). Accordingly, JP'765 teaches a method for improving the composition of the intestinal flora of a human (a mammal), comprising orally administering to a human whose intestinal flora is out of balance, a food in which

sphingosine is overabundant, or a pharmaceutical formulation comprising sphingosine and one or more excipients. In the examples, about 1 wt% of sphingolipid was used.

The Examiner notes that the instant application claims priority to Netherlands Patent Application No. 1022443 with a benefit date of 1/20/2003. However, although a certified copy of the foreign document has been filed, it is not in English and there has been no certified translation filed. For this reason, benefit to the foreign priority has not been perfected. See MPEP § 706.02(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6610835 (‘835). ‘835 teaches that sphingolipids are significant components of foods (col 3, lines 44-45). Sphingolipids, such as sphingosine and phytosphingosine (col 1, line 62), are highly bioactive compounds with potential to serve as carcinogenesis suppressors (col 7, lines 25-34). Undesirably, only a small amount of orally administered sphingolipid survives to the lower intestine, and it follows that even smaller amounts reach the more distant sites of the body (col 7, lines 39-43). The recommended system dosage amount is 0.1 mg/kg to 400 mg/kg of body weight per day (col 63, lines 35-40). There is a need to increase the bioavailablity of sphingolipids to improve their efficacy as a carcinogenesis suppressor (col 8, lines 32-37).

‘835 fails to teach fortifying foods with sphingolipids.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to fortify food with sphingolipids, including sphingosine and/or phytosphingosine, to increase the amount of the sphingolipid reaching the intestine. In this way, the bioavailability of the sphingolipid will be increased. Alternatively, it would have been obvious to administer a high dose pharmaceutical formulation comprising sphingosine and/or phytosphingosine to a human. In this way, the bioavailability of the sphingolipid will be increased. Regarding instant claims 14-15, ‘835 teaches the importance of the sphingolipid surviving to the intestine, and further teaches the carcinogenesis suppressor activity of the compounds (col 7, lines 25-34). Accordingly, '835 would suggest to the ordinary artisan that the composition could be used to treat cancer and the ordinary artisan would determine, without undue

experimentation, that the sphingolipid composition could be used to treat intestinal cancer, as this is present in the intestine where the drug comes into direct contact with. The weight percent ranges of 0.05 to 50 wt% (instant claim 2) and 1 to 10 wt% (instant claim 3) can be reached through routine optimization, as '835 teaches desired systemic dosage amounts of 0.1 mg/kg to 400 mg/kg of body weight per day. The ordinary artisan could readily translate, without undue experimentation, these desired dosage amounts into weight percentages in the final a dosage form. In this way, one would find the values of 0.05 to 50 wt% sphingolipid and 1 to 10 wt% sphingolipid. Regarding the instant limitation "a mammal whose intestinal flora is out of balance", the patient population to which the sphingosine of '835 will be administered is large. Owing to the ubiquity of humans with intestinal flora out of balance, and that the patient population of '835 is large, the patient population receiving the sphingosine according to the teaching of '835 will inherently comprise members whose intestinal flora is out of balance. As a composition cannot be separated from its properties, the sphingosine fortified food must inherently improve the intestinal flora of these patients.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

January 27, 2011